IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
MACON DIVISION

GAIL DEAN HARDISON, Individually as Surviving Spouse and GAIL DEAN HARDISON as Executor of the Estate of Lynwood Wilson Hardison, Jr., ***Plaintiff,*** **v.** **BIOMET, INC., *et al.*,** ***Defendants.***	**CIVIL ACTION NO.** **5:19-cv-00069-TES**

ORDER

Lynnwood Hardison filed suit on May 30, 2017, concerning an allegedly defective artificial hip implant and complications he suffered from it.[1] [Doc. 1]. Defendants (collectively referred to as "Biomet") are corporate entities that design, manufacture, market, promote, and sell the hip implant known as the Biomet M2a Magnum Hip System ("M2a Magnum"). [Doc. 66-1, ¶¶ 7—17].

Mr. Hardison's case is among thousands filed against Biomet. [Doc. 33, p. 1]. On October 2, 2012, the Joint Panel on Multidistrict Litigation ("JPML") consolidated the first actions involving Biomet's M2a Magnum and the M2a-38 artificial hip implants

[1] Unfortunately, Mr. Hardison died during the litigation. After his death, the Court granted Plaintiff's motion to substitute his wife, Gail Hardison, who had been named as his Executor, as Plaintiff in lieu of Mr. Hardison. [Doc. 65].

into a Multi-District Litigation action ("MDL") for coordinated pretrial proceedings. [*Id.*]; *See In re: Biomet M2A Magnum Hip Implant Prods. Liab. Litig.*, 896 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012); *see also* 28 U.S.C. § 1407. The JPML assigned the MDL to Judge Robert Miller, Jr. of the United States District Court for the Northern District of Indiana. *Id*. After extensive pretrial proceedings, Judge Miller transferred this particular matter to the Middle District of Georgia on February 22, 2019 [Doc. 50],which the court docketed on March 4, 2019. [Doc. 51]. The parties then engaged in case-specific discovery not covered in the MDL. [Doc. 62].

Now at the summary judgment stage, Plaintiff and Biomet filed five *Daubert* motions in limine seeking to exclude portions of the testimony of each other's expert witnesses. *See* [Doc. 109]; [Doc. 110]; [Doc. 111]; [Doc. 118]; [Doc. 119]. Additionally, Biomet has moved for summary judgment on all of Plaintiff's claims, primarily relying on the Court granting its *Daubert* motions. [Doc. 108]. Thus, it only makes sense that the Court discuss its decisions on the various *Daubert* motions before diving into the motion for summary judgment.

As described in detail below, the Court **GRANTS in part** and **DENIES in part** Biomet's motion for summary judgment [Doc. 108] and Biomet's motions to exclude testimony from Dr. Gannon [Doc. 109], Ms. Truman [Doc. 110], and Dr. Shapiro [Doc. 111]. Further, the Court **GRANTS in part** and **DENIES in part** Plaintiff's motion to exclude portions of Dr. Kurtz's testimony [Doc. 118] and **DENIES** Plaintiff's motion to

exclude portions of Dr. Bauer's testimony [Doc. 119] as outlined in this Order.

BACKGROUND

In order to better explain its decisions and to put the opinions in their proper factual context, the Court provides a summary of the facts and allegations. The Court will also discuss additional facts as they become relevant to the Court's analysis of the admissibility of the parties' witnesses and summary judgment arguments.

Mr. Hardison received a M2a Magnum artificial hip implant on February 4, 2009, at the age of 56. [Doc. 108-2, p. 84]. Mr. Hardison first sought treatment for right hip and groin pain from Dr. Pope on December 16, 2008. [*Id.,* p. 90]; [Doc. 135-3, ¶ 9]. During that visit, Dr. Pope noted Mr. Hardison was an "obese gentleman" who suffered from multiple conditions, including diabetes, hypertension and sleep apnea. [Doc. 108-2, p. 90]. Additionally, he noted that Mr. Hardison underwent lumbar spinal surgery in 2007. [*Id.*, pp. 57, 90]. After finding more conservative treatments had failed, Dr. Pope recommended total hip replacement surgery and chose to use the M2a Magnum. [*Id.*, pp. 90—91].

The M2a Magnum is a metal-on-metal ("MoM") implant and operates similarly to a functioning human hip. A physician must prescribe the hip implant as it is not commercially available. [Doc. 108-6, p. 2].

Biomet included an Instructions for Use ("IFU") inside the M2a Magnum packaging meant to advise the operating surgeon of the risks and adverse side effects

associated with the device. [*Id.*]. Under "Warnings", the IFU stated, "[e]xcessive activity, trauma and weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear." [*Id.*]. Dr. Pope did not recall reading this package insert. [Doc. 108-8, Pope Depo., p. 36:10-13].

Mr. Hardison experienced no complications during the hip replacement surgery. [Doc. 108-2, p. 86]. During his follow-up appointment on July 28, 2009, Dr. Pope noted his hip appeared "well healed[,]" but Mr. Hardison complained "about some lower back pain." [*Id.*, p. 92]. After the hip implant surgery, Mr. Hardison's wife stated his hip pain lessened, and he was able to perform activities like dancing. [Doc. 136-7, Hardison Depo., p. 76:5—23].

However, Mr. Hardison's pain management issues continued, and, in the years following his surgery, Mr. Hardison received treatment for hip and lower back pain, often associated with falls. *See* [Doc. 139-1, p. 17 (On August 24, 2010, Dr. Beringer examined Mr. Hardison after he fell out of a collapsed chair and was mainly complaining about lower back pain.)]; [Doc. 108-2, pp. 29—30 (On September 28, 2010, Mr. Boutselis, PA-C examined Mr. Hardison for back and right leg pain and referenced a second fall in December 2009.)]; [Doc. 139-1., p. 30 (On January 2, 2013, Mr. Hardison

sought treatment at Piedmont Orthopedics and Sports Medicine Complex after falling out of a golf cart while hunting.)].[2]

In 2014, Mr. Hardison continued to experience pain in his hip, leg, and lower back. [Doc. 108-2, p. 14]. Due to the continued pain, Mr. Hardison underwent a sacroiliac joint arthrodesis on December 29, 2014. [Doc. 139-1, pp. 37—38]; [Doc. 108-2, pp. 106—107].

Also in 2014, Mr. Hardison's blood tests revealed increased cobalt and chromium levels on two occasions. [Doc. 139-1, pp. 33—36]. In 2015, Mr. Hardison experienced an increase in right hip and lower back pain. [*Id.*, pp. 42—50]; [Doc. 108-2, p. 63]. Mr. Hardison then saw Dr. Flandry for this continued and increased pain. In August 2015, Dr. Flandry performed exploratory surgery for repair of his abductor muscles and found "metallosis staining of the pseudo capsule but no evidence of pseudotumor." [*Id.*, pp. 62—63].

Dr. Raurk then examined Mr. Hardison and performed revision surgery on Mr. Hardison's right hip on October 20, 2015. [*Id.*, pp. 65—67]. Dr. Raurk indicated the evidence pointed to "metal on metal bearing surface wear reaction and soft tissue

[2] There is some confusion whether the pain originated from his back or hip during this time frame. For instance, in January 2011 when Mr. Hardison had a follow-up appointment with Dr. Pope, Mr. Hardison was using an assistive walking device that he attributed to back and sacral fracture issues, not his hip. [Doc. 108-2, p. 96]; *see also* [*Id.*, p. 99 (During Mr. Hardison's follow-up appointment with Dr. Pope in 2012, Mr. Hardison associated his pain with back issues.)].

reaction to that." [*Id.*, p. 65] After this revision surgery, Mr. Hardison developed a post-operative infection and required follow-up surgeries. [*Id.,* pp. 71—76].

While his health did initially show some improvement after the revision surgery, Mr. Hardison's health continued a downward trajectory until his death on May 3, 2019. [Doc. 139-1, p. 209]. Medical records suggest Mr. Hardison suffered from several medical issues at this time, including morbid obesity, cellulitis of the right lower leg, diabetes, hypertension, chronic pain, moderate malnutrition, and suspected respiratory insufficiency. [Doc. 108-2, p. 8]. The listed immediate causes on Mr. Hardison's Death Certificate were respiratory failure and chronic obstructive pulmonary disease. [*Id.*].

Mr. Hardison filed suit against Biomet on May 30, 2017. *See* [Doc. 1]. After Mr. Hardison's death, Gail Dean Hardison, his wife, was substituted as the plaintiff, filing suit as executor of the estate of Mr. Hardison and individually as surviving spouse. [Doc. 65]. In Ms. Hardison's Amended Complaint, she asserts claims for: (1) Strict Liability – Design; (2) Strict Liability – Failure to Warn; (3) Breach of Express Warranty; (4) Violation of the Georgia Fair Business Practices Act ("GFBPA"); (5) Negligence (design, manufacturing, and warnings), (6) Negligent Misrepresentation; (7-8) Breach of Implied Warranties; (9) Loss of Consortium; and (10) Wrongful Death. *See generally* [Doc. 68]; *see also* [Doc. 135-3, ¶ 84]. Plaintiff seeks double or triple damages, attorneys' fees, and punitive damages. [Doc. 68, pp. 34—35]; [Doc. 135-3, ¶ 85].

In sum, Plaintiff claims the release of cobalt and chromium debris and metal ions into Mr. Hardison's body—caused by the device failure—resulted in "significant harm [to her husband], including but not limited to physical injury and bodily impairment, debilitating lack of mobility, conscious pain and suffering, elevated metal ion levels, and loss of earnings." [Doc. 68, ¶¶ 1, 62, 87]; [Doc. 135-3, ¶ 90].

Plaintiff served her expert reports designating Dr. Jeffrey Shapiro (an orthopedic surgeon), Dr. Francis Gannon (a pathologist), and Mari Truman (a professional engineer), as her retained case-specific experts. [Doc. 108-13]; [Doc. 135-3, ¶ 91]. Plaintiff also designated Dr. George Kantor as Plaintiff's retained common-issue expert. [Doc. 108-13]; [Doc. 135-3, ¶ 92]. Plaintiff's common-issue expert did not perform any case-specific analysis of Plaintiff's case. [Doc. 108-13]; [Doc. 135-3, ¶ 93]. Plaintiff did not identify any non-retained treating expert nor disclose that any non-retained expert would provide any causation opinion. [Doc. 108-13]; [Doc. 135-3, ¶ 94].

Biomet requests that the Court exclude Plaintiff's case-specific experts' causation (as well as other) opinions and grant its motion for summary judgment. [Doc. 108]; [Doc. 109]; [Doc. 110]; [Doc. 111]. Further, Plaintiff seeks to exclude portions of two of Biomet's expert witnesses' testimony. [Doc. 118]; [Doc. 119].

DISCUSSION

A. Motions in Limine

1. Standard

Rule 702 of the Federal Rules of Evidence provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rulings on the admissibility of expert testimony—like all evidentiary rulings—are in the exercise of the Court's discretion. *See Burchfield v. CSX Transp., Inc.*, 636 F.3d 1330, 1333 (11th Cir. 2011). Trial courts are to act as "gatekeepers" to ensure that speculative and unreliable opinions do not reach the jury. *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 589, n.7 (1993). "This gatekeeping role, however, is not intended to supplant the adversary system or the role of the jury: vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *United States v. Ala. Power Co.*, 730 F.3d 1278, 1282 (11th Cir. 2013). Expert testimony is admissible if "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable . . . ; and (3) the testimony assists the trier of fact . . . to understand the evidence or to

determine a fact in issue." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (quoting *City of Tuscaloosa v. Harcros Chems. Inc*., 158 F.3d 548, 562 (11th Cir. 1998)). The " 'burden of establishing qualification, reliability and helpfulness' " lies with the party offering the expert opinion. *McClain v. Metabolite lnt'l. Inc*., 401 F.3d 1233, 1238 (11th Cir.2005) (quoting *Frazier*, 387 F.3d at 1260).

"While scientific training or education may provide possible means to qualify, experience in a field may offer another path to expert status." *Frazier*, 387 F.3d at 1260—61. Federal Rule of Evidence 702 provides that an expert's qualification may be based on "knowledge, skill, experience, training, or education." Fed. R. Evid. 702 advisory committee's note (2000 amends.) ("Nothing in this amendment is intended to suggest that experience alone . . . may not provide a sufficient foundation for expert testimony."). Thus, "there is no mechanical checklist for measuring whether an expert is qualified to offer opinion evidence in a particular field." *Santos v. Posadas De Puerto Rico Assocs. Inc*., 452 F.3d 59, 63 (1st Cir. 2006). Further, "while an expert's overwhelming qualifications may bear on the reliability of his proffered testimony, they are by no means a guarantor of reliability. . . . [Eleventh Circuit] caselaw plainly establishes that one may be considered an expert but still offer unreliable testimony." *Frazier*, 387 F.3d at 1261 (citing *Quiet Tech. DC–8, Inc. v. Hurel–Dubois UK Ltd*., 326 F.3d 1333, 1341—42 (11th Cir. 2003)).

In assessing whether an expert's methodology is reliable, the Court generally should consider the following factors: "(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential error rate of the technique; and (4) whether the technique is generally accepted in the scientific community." *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1327 (11th Cir.2014) (per curiam). These factors, of course, represent a non-exhaustive list and " 'do not constitute a definitive checklist or test.' " *Id*. (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)). "While those factors may help in assessing the reliability of scientific or experience-based expert testimony, the district court's 'gatekeeping inquiry must be tied to the facts of a particular case.' " *Id*. (quoting *Kumho Tire*, 526 U.S. at 150).

In its gatekeeping role, the Court's focus must be on the reliability of the testimony, not simply whether it fits within the narrow confines of lawyer-urged litmus tests. While " 'each stage of the expert's testimony [must] be reliable, . . . each stage must [also] be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules.' " *Frazier*, 387 F.3d at 1262 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir.1999)). The Court's goal is to ensure that an expert " 'employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.' " *Id*. at 1260 (quoting *Kumho Tire*, 526 U.S. at 152). "Sometimes the specific [traditional] *Daubert* factors will aid in determining reliability;

sometimes other questions may be more useful." *Id*. at 1262. Testimony that the parties plan to present to a jury must be " 'properly grounded, well-reasoned, and not speculative.' " *Id*. (quoting Fed. R. Evid. 702 advisory comm. note (2000 amends)).

Finally, the Court must assess whether the expert testimony is helpful to the trier of fact. This factor turns on whether the expert testimony "concerns matters that are beyond the understanding of the average lay person." *Frazier*, 387 F.3d at 1262. "Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." *Id*. at 1262–63. "Nor does expert testimony help the trier of fact if it fails to 'fit' with the facts of the case." *Stoner v. Fye*, No. 5:15-cv-102 (CAR), 2017 WL 2434461, at *4 (M.D. Ga. June 5, 2017) (quoting *McDowell v. Brown*, 392 F.3d 1283, 1299 (11th Cir. 2004)). "Expert testimony lacks 'fit' when 'a large analytical leap must be made between the facts and the opinion.' " *Id.* (quoting *McDowell*, 392 F.3d at 1299); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. "Thus, the court may exclude otherwise reliable testimony if it does not have 'sufficient bearing on the issue at hand to warrant a determination that it [is *helpful* to the trier of fact].' "*Fye*, 2017 WL 2434461, at *4 (quoting *Bitler v. A.O. Smith Corp*., 400 F.3d 1227, 1234 (10th Cir. 2005)). "At all times when scrutinizing the reliability and relevance of

expert testimony, a court must remain mindful of the delicate balance between its role as a gatekeeper and the jury's role as the ultimate fact-finder." *Id.*

2. Biomet's Motion to Exclude Portions of Dr. Shapiro's Testimony [Doc. 110]

Dr. Shapiro reviewed Mr. Hardison's medical records on Plaintiff's behalf and gave medical causation and failure-to-warn opinions. [Doc. 110-2, pp. 6—8] He is a practicing orthopedic surgeon who is familiar with the causes of total hip replacement failure. [*Id.*, p. 2].

Dr. Shapiro's relevant medical causation and failure-to-warn opinions are: (1) that the M2a Magnum prematurely failed by producing excess metal debris necessitating a revision surgery, (2) as a result of the revision surgery with complications, Mr. Hardison suffered a post-revision infection and two follow-up surgeries that contributed to his overall health conditions, (3) Mr. Hardison's prolonged exposure to metal debris caused tissue damage to his right abductor muscles, (4) as a result of the tissue damage to the right abductor muscle, he suffered from an altered gait resulting in post-revision falls that negatively impacted his overall health conditions, (5) revision surgery complications and falls negatively impacted or exacerbated his other health conditions resulting in his downward health decline and were a substantial contributing factor to his death, (6) Mr. Hardison's other medical conditions did not play a role in the premature failure of the device, and (7) Biomet

failed to provide proper warnings of the implant's risk and a surgeon would not have used the device if they had been fully appraised of the risks. [Doc. 131, pp. 3—4]; [Doc. 110-2, pp. 6—8].

Biomet seeks to "exclude Dr. Shapiro's case-specific opinions offered by Plaintiff as to causation and failure to warn under Federal Rule of Evidence 702." [Doc. 110-1, p. 1].

a. Dr. Shapiro's Failure-to-Warn Opinion

Dr. Shapiro seeks to opine that Biomet's IFU and marketing activities failed to provide proper warnings of the risks associated with the M2a Magnum and the resulting generation of metal debris. [Doc. 108-14, p. 6]. Further, Dr. Shapiro stated that "[h]ad Mr. Hardison and his implanting surgeon been aware of the true risks associated with Biomet's product, they likely would have selected a safer alternative implant." [Doc. 110-2, p. 8].

First, a failure-to-warn claim can be brought in either the form of a failure to

properly communicate a warning or a failure to give an adequate warning.[3] Plaintiff's only valid failure-to-warn claim is in the form of a failure to communicate a warning, which as discussed below is supported by expert testimony from Dr. Shapiro and Ms. Truman. [Doc. 135-1, p. 23].

Dr. Shapiro's orthopedic expertise qualifies him to opine about the substance of Biomet's warning and how the warning might have affected a surgeon's decision to use the device. *Cason v. C. R. Bard, Inc.*, No. 1:12-CV-1288-HMS, 2015 WL 9913809, at *10 (N.D. Ga. Feb. 9, 2015); *see Chambers v. Boehringer Ingelheim Pharm., Inc.*, 4:15-CV-00068 (CDL), 2018 WL 849081, at *5–6 (M.D. Ga. Jan. 2, 2018), on reconsideration in part, 2018 WL 847246 (M.D. Ga. Feb. 13, 2018). However, as to the substance of the warning, Dr. Shapiro's testimony about the contents of the IFU are irrelevant because Dr. Pope never

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[3] Under Georgia law, a manufacturer breaches its duty to warn:

> if it fails to (1) adequately communicate the warning to the ultimate user or (2) fails to provide an adequate warning of the product's potential risks. A failure to communicate a warning can involve issues like the location and presentation of the warning. The failure to adequately warn, by contrast, depends upon the substance of the warning.

Brown v. Sirchie Acquisition Co., LLC, No. 1:16-CV-175-SCJ, 2017 WL 4082690, at *5 (N.D. Ga. 2017) aff'd, 694 F.App'x 745 (11th Cir. 2017) (per curiam) (quoting *Bryant v. BGHA Inc.*, 9 F. Supp. 3d. 1374, 1383 (M.D. Ga. 2014)). "Proximate cause is a necessary element for both forms of warning defect claims." *Bryant*, 9 F. Supp. 3d. at 1395 (citing *Wilson Foods Corp. v. Turner*, 460 S.E.2d 532, 534 (Ga. Ct. App. 1995)). Plaintiff appears to focus on her failure to communicate a warning claim. [Doc. 135-1, p. 23]. Further, Plaintiff's failure-to-adequately-warn claim would be facially deficient. "[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk[.]" *Bryant*, 9 F. Supp. 3d. at 1395 (quoting *Turner*, 460 S.E.2d at 534). Dr. Pope was clear that he never read the IFU. [Doc. 137-5, Pope Depo., p. 36:10-13 ("Q. Do you know if you've ever seen in the package insert the written warnings that were provided by Biomet with the Magnum? A. I've never seen – I've never seen those.")]. Thus, any claim about the substance of the warning fails as a matter of law. However, "failure to read a warning does not bar recovery when the plaintiff is challenging the adequacy of the efforts of the manufacturer or seller to communicate the dangers of the product to the buyer or user." *Bryant*, 9 F. Supp. 3d. at 1395 (quoting *Turner*, 460 S.E.2d at 534). Thus, Plaintiff could still have a plausible claim for failure to communicate a warning.

read the warning. Simply put, Dr. Shapiro's opinion about how a medical professional would understand a warning in the IFU is irrelevant when the surgeon who selected the device and performed the operation never read the warning. As to how a warning label might have affected a surgeon's decision to use the device, Dr. Shapiro can opine about how a surgeon would have reacted to a properly-communicated warning. *See* [Doc. 110-2, p. 8 (Dr. Shapiro stated that "[h]ad Mr. Hardison and his implanting surgeon been aware of the true risks associated with Biomet's product, they likely would have selected a safer alternative implant.")]; *see also Cason*, 2015 WL 9913809, at *10 (collecting cases).

Next, the Court considers Dr. Shapiro's opinions about how Biomet communicated its warnings. Biomet contends that Dr. Shapiro is unqualified to give his failure to communicate a warning opinion because he has not worked for the Food and Drug Administration ("FDA") and has no regulatory expertise. [Doc. 162, p. 2]. Further, Biomet asserts that Dr. Shapiro was "simply offering an 'off-the-cuff' opinion as to the inadequacy of the warning" that is "subject to exclusion in the highly regulated context of prescription medical device[s]." [*Id.*, p. 5].

As to qualifications, "courts have found that experts without [regulatory or warning drafting] experience were not qualified to testify regarding the adequacy of the warnings accompanying a medical device." *See Cason*, 2015 WL 9913809, at *10 (collecting cases). As to reliability, "[t]he first step in providing reliable warning

opinions (that is also helpful to a jury) is to tether those opinions to the specific labels and marketing practices that were in place when the plaintiff actually [received the implant]." *Kaufman v. Pfizer Pharm., Inc.*, No. 1:02-CV-22692, 2011 WL 7659333, at *9 (S.D. Fla. Aug. 4, 2011) (citing *Quiet Tech. DC–8, Inc.*, 326 F.3d at 1342). "The second step in providing a reliable opinion is to apply expert analysis or a sound methodology to the labels or practices at issue, to support the opinions that the warnings were inadequate." *Id.* at *10 (citing *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002).

Dr. Shapiro opined about how Biomet delivered the warnings. For instance, he stated in his deposition that "surgeons don't really read the inserts in the boxes." [Doc. 110-3, Shapiro Depo., p. 104:18—23]. Simply put, Dr. Shapiro lacks the regulatory background to offer this opinion, is unfamiliar with the FDA rules and regulations, and did not introduce any semblance of an industry standard aside from his own belief. *See* [*Id.*, pp. 139:9—13, 142:9—13].

Thus, the Court excludes Dr. Shapiro's opinions about the communication of the warnings because he is not qualified and excludes his opinion about the substance of the warnings inside the IFU as irrelevant. However, Dr. Shapiro is qualified to testify as to how a surgeon would react to a properly-communicated warning and whether that would affect a surgeon's willingness to use the device.

b. Dr. Shapiro's Causation Opinion

Biomet challenges both Dr. Shapiro's qualifications and methodology to render his causation opinions. As noted above, Dr. Shapiro's causation opinions are (1) the hip implant failed due to non-patient factors by producing metal debris necessitating revision surgery, (2) as a direct result of the revision surgery with complications, Mr. Hardison suffered an infection and needed two follow-up hip surgeries, (3) the prolonged exposure to metal debris caused right hip tissue damage, including damage to his right abductor muscle group (4) as a result of the muscle damage, he suffered from an altered gait and instability contributing to post-revision falls, (5) the post-revision falls and the direct results from the revision surgery negatively impacted his overall health and were a substantial contributing factor to his ultimate death. [Doc. 131, pp. 3—4]. Essentially, Biomet seeks to disrupt this causal chain by arguing Dr. Shapiro does not employ a reliable methodology throughout his causation analysis. [Doc. 110-1, p. 13—19]. Biomet makes specific objections to Dr. Shapiro's opinions (1) that "premature revision was attributable to the device", (2) "blaming a 'cascade' of health effects on the device, particularly considering Mr. Hardison's confounding circumstances and co-morbidities", and (3) that "Mr. Hardison's death was caused by a design defect." [Doc. 110-1, pp. 12, 16, 20]. Further, Biomet seeks to exclude Dr. Shapiro's entire opinion because it argues Dr. Shapiro is unqualified. [Doc. 110-1, pp. 11—12].

i. Dr. Shapiro's Qualifications and Conflicts with Treating Physicians

First, the Court considers Biomet's more general concerns with Dr. Shapiro's testimony. Biomet argues that Dr. Shapiro's qualifications are questionable because he has transitioned away from performing hip implants and his method is unreliable because he second-guessed the judgment of at least one physician whom he purportedly relied upon when he "explicit[ly] rejected Dr. Raurk's testimony that Mr. Hardison did not have permanent muscle damage." [Doc. 162, pp. 6—7]; [Doc. 110-1, pp. 11—12].

Dr. Shapiro's experience as a practicing orthopedic surgeon qualifies him to make causation opinions. He has spent decades in the field of orthopedics, specializing in hip and knee surgery. Biomet's contention that Dr. Shapiro's "present experience is an imperfect fit with this case" merely because he has transitioned his practice recently away from hip implants to knee surgeries does not render his testimony inadmissible.[4] [Doc. 110-1, pp. 11—12]; *see* [Doc. 110-2, pp. 2, 18—21].

Next, Biomet argues that Dr. Shapiro's "conflicting assessment" with Dr. Raurk's observation that there was no permanent muscle damage, "alone renders [his] opinion suspect." [Doc. 110-1, p. 13]. While Dr. Raurk may have been in a better position to observe potential muscle damage than Dr. Shapiro, Dr. Shapiro did not rely solely on

[4] While this fact may ultimately prove to be a target-rich environment for cross examination, it does not, in and of itself, render his testimony inadmissible.

Dr. Raurk's opinion in coming to his conclusions. Accordingly, Dr. Shapiro's disagreements with Dr. Raurk would also be appropriate subjects for cross-examination, but do not render his opinions inadmissible.

ii. Differential Diagnosis Standard

Biomet seeks to specifically exclude several of Dr. Shapiro's causation opinions because he performed a "less than vigorous" differential diagnosis to reach his conclusion. [Doc. 162, pp. 7—9]; [Doc. 110-1, pp. 13—16]. Conversely, Plaintiff argues that Dr. Shapiro correctly performed a differential diagnosis and ruled out other likely causes for the implant failure, need for revision surgery, tissue damage, and subsequent declining health and death. [Doc. 131, pp. 16—19].[5]

"[D]ifferential diagnosis is a scientifically accepted methodology [which] meets the *Daubert* guiding factors for district judges in deciding reliability." *Chapman v. Proctor & Gamble Distrib., LLC*, 766 F.3d 1296, 1309 (11th Cir. 2014). "Differential diagnosis" is "a medical process of elimination whereby the possible causes of a condition are considered and ruled out one-by-one, leaving only one cause remaining." *Id*. at 1308 (citing *Hendrix v. Evenflo Co*., 609 F.3d 1183, 1195 (11th Cir. 2010)). A "differential diagnosis includes three steps: (1) the patient's condition is diagnosed, (2) all potential

[5] Plaintiff primarily points to—as proof for a proper differential diagnosis—Dr. Shapiro's statements that he reviewed all of the medical records and ruled out other possible causes. [Doc 131, pp. 16—22]. However, "an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient." *McClain,* 401 F.3d at 1253.

causes of the ailment are considered, and (3) differential etiology is determined by systemically eliminating the possible causes." *Id*.

As noted in *Moore,* experts relying on differential diagnosis must: "(1) generate 'a comprehensive list of possible causes that are generally capable of causing' the condition; (2) 'systematically and scientifically rule [ ] out specific causes until a final, suspected cause remains'; and (3) 'show through reliable evidence that the remaining cause ruled in as actually being capable of causing the condition.' " *Moore v. Wright Med. Tech., Inc*., No. 1:14-CV-62, 2016 WL 1316716, at *4 (S.D. Ga. Mar. 31, 2016) (quoting *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1343 (11th Cir. 2010)).[6]

The Eleventh Circuit and other circuits have found that an expert "must provide a reasonable explanation as to why 'he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause' " of the plaintiff's injury." *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (collecting circuit case law); *Hendrix,* 609 F.3d at 1197 (indicating that "an expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation.") (citation omitted).

[6] In *Moore,* the Court found that the medical expert performed a proper differential diagnosis when he "rul[ed] out surgical error and Otis Moore's weight and activity levels as causes of the device failure and rul[ed] in micromotion and fretting corrosion." 2016 WL 1316716, at *4.

Further, expert testimony may not rely on mere temporal proximity or the *ipse dixit* of the expert. *Guinn*, 602 F.3d at 1255–56 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.") (citing *Joiner*, 522 U.S. at 146); *McClain*, 401 F.3d at 1243 ("[P]roving a temporal relationship . . . does not establish a causal relationship . . . [S]imply because a person takes drugs and then suffers an injury does not show causation.").

iii. Dr. Shapiro's Opinion that the Hip Implant Caused Muscle Weakness and the Need for Revision Surgery

First, as to Dr. Shapiro's opinion that the hip implant failure caused muscle damage and the need for revision surgery, Dr. Shapiro did not perform an adequate differential diagnosis because he failed to "rule out" other causes. Essentially, Dr. Shapiro based his opinion on three separate causation findings: (1) that the hip implant caused the metal debris, (2) that the hip implant did not fail because of patient factors, (3) that the medical debris caused the muscle weakness and need for revision surgery.

Dr. Shapiro opined that the hip implant caused the metal debris. Dr. Shapiro stated that he considered "back problems, stenosis, and the need for spinal surgery" in finding the effects of the hip implant were separate and distinct from other medical conditions. [Doc. 110-2, pp. 6—7.] Dr. Shapiro expanded on his rationale in his supplemental report, stating, in part, "the spinal implants could not have been a source

of cobalt and chromium elevation." [Doc. 110-4, p. 3]. Accordingly, the Court finds Dr. Shapiro performed an appropriate differential diagnosis for the metal debris coming from the M2a Magnum.

Next, the Court turns to Dr. Shapiro's opinion that the M2a Magnum did not fail because of patient factors. Biomet argues that Dr. Shapiro should have considered patient factors that can affect device performance, like lumbar and sacral complications, high body mass, and a history of falling.[7] [Doc. 110-1, p. 15 (citing [Doc. 110-3, Shapiro Depo., pp. 134:20—135:18, 137:12—14, 155:25—156:24])].

Dr. Shapiro does rule out some patient factors and other potential causes of hip implant failure. For instance, Dr. Shapiro eliminated surgical error in implanting the device. [Doc. 110-2, p. 6]. Further, Dr. Shapiro provided a rationale for ruling out traumatic falls in his deposition.[8] Still, Dr. Shapiro failed to explicitly rule out other patient factors, like weight and physical activity, even though he was aware weight and activity levels could be causes of premature device failure, as also noted in the IFU.[9] Absent an analysis of how Plaintiff's lifestyle and health conditions could not have caused the metal wear, Dr. Shapiro's analysis contains an analytical gap in identifying

[7] Dr. Shapiro acknowledged that "activity, trauma and weight" have been implicated in premature device failures. [Doc. 110-3, Shapiro Depo., p. 134:5—10].

[8] Dr. Shapiro stated he does not believe Mr. Hardison's history of falls could have caused implant failure because the falls were not severe enough. [Doc. 110-3, Shapiro Depo., pp. 134:2—136:24].

[9] Dr. Shapiro stated he was aware of Mr. Hardison's obesity. [*Id.*, p. 137:12—14].

the cause of the implant's failure.[10] Thus, Dr. Shapiro cannot opine as to the cause of the device failure.

Further, Dr. Shapiro did not rule out other causes of muscle tear damage. Dr. Shapiro stated in his deposition that he is unable to "rule out" "all other causes" of "intrasubstance tears", like aging and trauma. [Doc. 110-3, Shapiro Depo., pp. 213:17—214:22 (stating in part "Q: How did you rule out all of the causes of intrasubstance tears? A: Well, I can't. I can just say what was there . . . But, if you look in the totality of the whole picture of why we're here, more likely than not the weakening of the muscle and his intrasubstance observation and the MRI that showed, you know, the MRI shoulder intrasubstance tears, when you put it all together, it's probably the result of the metal, metal debris.")]. Dr. Shapiro did not correctly rule out the other potential causes of the muscle tears and, instead, appears to rely on temporal proximity for his reason for the muscle damage. Accordingly, the Court finds an analytical gap between a finding of metal debris and the cause of the muscle weakness; thus, the Court exercises its discretion and excludes this opinion.

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[10] Based on the deposition testimony and Dr. Shapiro's supplemental report, Dr. Shapiro knew that these factors were alleged by Biomet as the sole cause of Mr. Hardison's injury. First, Biomet pointed to weight, activity, and trauma as possible causes during the deposition. Moreover, the Court takes particular note that—while Dr. Shapiro was not asked specifically why he did not rule out these causes in his deposition—he submitted a supplemental report that contained no mention of these potential causes. Further, in the supplemental report, Dr. Shapiro stated he reviewed all of Biomet's expert witnesses, including Dr. Schmidt's Report. [Doc. 110-4, p. 12]. Dr. Schmidt opined that the "elevated cobalt and chromium levels . . . reflect[ed] increased wear of his implant due to his morbid obesity and altered lower body mechanics, as well as inadequate renal clearance of the prosthetic wear which normally occurs in all prosthetic designs." [Doc. 108-20, p. 11]. Dr. Shapiro—after reviewing these findings—should have expanded on his deficient differential diagnosis in his original report.

iv. Dr. Shapiro's Opinion the Revision Surgery and Muscle Damage Contributed to Mr. Hardison's Downward Health Decline and Death

The Court now turns to Dr. Shapiro's opinions about whether the device failure contributed to Mr. Hardison's health decline and death. First, Dr. Shapiro cannot merely conclude that because the revision surgery and muscle damage could be a cause of Mr. Hardison's subsequent health decline and death that the revision surgery was a cause. "[A]lthough the differential diagnosis technique is well accepted . . . [, a finding] that all possible causes are causes does not appear to have gained general acceptance in the medical and scientific communities." *Guinn*, 602 F.3d at 1255 (quoting *Cano v. Everest Minerals Corp*., 362 F.Supp.2d 814, 846 (W.D. Tex. 2005)).

Further, Dr. Shapiro failed to perform a proper differential diagnosis for his opinion that the revision surgery and muscle damage was a cause of Mr. Hardison's health decline and death. The Court finds the below exchange with Dr. Shapiro particularly telling:

> Q: Are you able to say to a reasonable degree of medical certainty that had Mr. Hardison not required a revision he would not have had an exacerbation of COPD, respiratory failure, hypoxia, dementia, diabetes, renal failure and an inability to walk?
>
> A: So, given his age and his function at the time that all this happened I would say more likely than not if he had a traditional hip replacement and didn't have to have the hip removed and revised I would think that more likely than not this may have happened, at least not at this stage.

[Doc. 110-3, Shapiro Depo., pp. 240:16—241:2]. But Dr. Shapiro never explains why he ruled out those co-morbidities. Further, when Dr. Shapiro stated he should have considered them and would if there was an addendum to his report. [*Id*., p. 237:17—21 ("Q. Is there a reason that you omitted those facts? A. There's no reason. But, I should have included that in the report. And in the fact that there's an addendum I will include that.")]; *see* [Doc. 110-4, pp. 2—3]. But Dr. Shapiro failed to provide a discussion ruling out the co-morbidities in his supplemental report. *See generally* [Doc. 110-4]. Again, because Dr. Shapiro did not provide a complete differential diagnosis, the Court excludes this opinion.

v. Summary of Dr. Shapiro's Admissible Causation Opinions

Dr. Shapiro did not perform an adequate differential diagnosis in his initial report and failed to properly expand on his analysis when given the opportunity during his deposition and supplemental report. Given the gaps in analytical reasoning discussed above, the Court concludes much of Dr. Shapiro's rational is little more than *ipse dixit* or based on temporal proximity, both of which are inappropriate bases for admitting expert testimony. *Guinn*, 602 F.3d at 1255–56; *McClain*, 401 F.3d at 1243.

The Court appreciates that Mr. Hardison's multiple health conditions render it difficult to identify the cause of implant failure and resulting damage, health decline, and death. However, "[a]s the gatekeeper, it is the Court's job to ensure situations with such little evidence do not lead to final expert conclusions based on speculation." *Nat'l*

Sur. Corp. v. Georgia Power Co., No. 2:17-CV-68-RWS, 2019 WL 4394403, at *6 (N.D. Ga. 2019) (citing *Daubert*, 509 U.S. at 591).

To summarize, Dr. Shapiro may not opine that:

1. Mr. Hardison's other medical conditions did not play a role in the premature failure of the device.
2. The metallosis negatively affected the tissue.
3. The revision surgery complications and falls negatively impacted or exacerbated his other health conditions resulting in his downward health decline and was a substantial contributing factor to his death.

Dr. Shapiro's admissible opinions include that:

1. The metal debris came from the M2a Magnum.
2. The direct result of the revision surgery with complications caused a post-revision infection, several months of treatment, and two follow-up surgeries.

3. Biomet's Motion to Exclude Portions of Dr. Gannon's Testimony [Doc. 109]

Dr. Gannon, a pathologist, opined in his expert report that "adverse reaction to metal debris [led] to long term muscle/tissue damage and early right hip implant failure in this patient." [Doc. 109-2, p. 4]. Further, in Dr. Gannon's deposition, he opined that necrosis "led to his pain, which led to revision surgeries, and also contributed to his instabilities, his falls, and eventually his death." [Doc. 109-3, Gannon Depo., pp. 100:15—101:10]; *see* [Doc. 109-1, p. 2]. Specifically, Dr. Gannon's deposition opinion

asserts that the necrosis started a clinical progression that limited Mr. Hardison's ability to walk—which worsened his diabetes and congestive heart failure because of his inability to exercise—and contributed to his early death. [Doc. 109-3, Gannon Depo., pp. 103:1—105:19].

Biomet asks the Court to exclude parts of Dr. Gannon's deposition testimony. Biomet argues that his causation opinions that tissue necrosis led to muscle weakness and implant failure which in turn led to Mr. Hardison's health decline and death does not meet the standards for admissibility in Rule 702 and *Daubert* because he doesn't rely on any testing, study, differential diagnosis, or methodology to reach his conclusions. [11] [Doc. 109-1, p. 2]. Biomet also challenges the admissibility of Dr. Gannon's causation opinion as to necrosis because Dr. Gannon failed to rule out Mr. Hardison's diabetes as a potential cause. [*Id.,* p. 5]. Plaintiff argues Dr. Gannon performed a proper differential diagnosis. [Doc. 134, p. 16].

As to Dr. Gannon's opinion that the metal debris caused necrosis, Biomet argues that Dr. Gannon did not consider—or could not rule out—diabetes as the cause of

[11] Further, Biomet, relying on Federal Rule of Civil Procedure 26(a)(2)(B), asserts that one of Dr. Gannon's causation opinions—offered only in his deposition and was not in his report—cannot be used at trial. [Doc. 109-1, p. 2]; *see* [Doc. 134, p. 3]. This opinion is that tissue necrosis "led to his pain, which led to revision surgeries, and also contributed to his instabilities, his falls, and eventually his death." [Doc. 109-3, Gannon Depo., pp. 100:15—101:10]; *see* [Doc. 109-1, p. 2]. This opinion is similar to Dr. Gannon's opinion stated in his Report that an "adverse reaction to metal debris [led] to long term muscle/tissue damage and early right hip implant failure in this patient." [Doc. 109-2, p. 4]. However, Dr. Gannon's deposition opinion concerns not only immediate harm but also future harm such as falls, an exacerbation of his other conditions, and his death. As to those opinions, the Court need not reach the proper disclosure issue because Dr. Gannon's causation analysis is also not an adequate differential diagnosis.

necrosis. [Doc. 109-1, p. 5]. Dr. Gannon stated in his deposition that the odds would be "astronomical" that diabetes caused necrosis "because it would have to be a very specific vessel in the hip capsule" but Dr. Gannon admitted that it was possible. [Doc. 109-3, Gannon Depo., pp. 124:19—125:9]. The Court finds this rationale sufficient to rule out diabetes as a possible cause for the purposes of admissibility. Dr. Gannon further ruled out necrosis being linked to tissue trauma and from his prior abductor repair surgery. [*Id.*, pp. 110:22—111:8]. As to the long-term muscle damage, Dr. Gannon states he identified long-term damage based on "patient's symptomatology" and "tissues that are involved, tendons, ligaments, things like that, take a long time to be injured." [*Id*., p. 118:1—13]. Accordingly, the Court finds Dr. Gannon's analysis sufficient to show to a reasonable degree of medical certainty that necrosis developed because of the metal debris and led to long-term muscle damage.

Next, the Court considers the clinical progression of the necrosis and revision surgery later leading to instability, exacerbated co-morbidities, falls, and contributing to his ultimate death. Plaintiff argues that her expert reviewed the relevant medical record and stated he considered other health conditions. [Doc. 109-3, Gannon Depo., pp. 101:16—21, 105:23—106:3]; [Doc. 134, pp. 16—19]. But, as discussed above with Dr. Shapiro, the expert cannot merely state that he performed the requisite analysis. "[A]n expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient."

McClain, 401 F.3d at 1253. Here, Dr. Gannon failed to rule out possible sole causes as is needed for a proper differential diagnosis of Plaintiff's health decline and death.

First, Dr. Gannon did rule-in necrosis-caused instability as leading to Mr. Hardison's health decline. When asked how necrosis and instability aggravated Mr. Hardison's congestive heart failure, Dr. Gannon stated that his decreased mobility limited his ability to exercise and lose weight, "which would have helped decrease his hypertension, which would have put less burden on his heart, because congestive heart failure is failure to get all of the blood . . . [a]nd so increasing activity allows the heart to get stronger, and decreasing weight would help with his hypertension but also with his Type II diabetes." [Doc. 136-1, Gannon Depo., p. 106:10—25]. However, Dr. Gannon failed to consider other possible sole causes, including Mr. Hardison's diabetes management in reaching his conclusions. [*Id.*, p. 107:1—7 ("Q. And as far as the impact of his – the clinical progression on his Type II diabetes, did you take into account any other parts of his diabetes management when you made that conclusion? A. No")].

Dr. Gannon's analysis is similarly deficient as to the cause of Mr. Hardison's death. While Dr. Gannon ruled-in instability as a possible cause (as well as his other co-morbidities), he failed to rule-out the co-morbidities as sole causes. [*Id.*, pp. 105:23—106:3 (stating that all co-morbidities contributed to Mr. Hardison's ultimate passing but were hastened by his immobility)].

Given Mr. Hardison's multiple health conditions, the Court finds Dr. Gannon's opinion overly speculative as to his immobility causing his health decline and death.

Dr. Gannon sufficiently concluded that metal debris caused necrosis and long-term muscle damage but failed to perform an adequate analysis as to the extent the muscle damage caused his subsequent health decline along with his other co-morbidities. Accordingly, the Court will admit Dr. Gannon's analysis as to the development of the necrosis and long-term muscle damage but exclude his causation testimony as to the necrosis leading to Plaintiff's overall health decline and contributing to his death.

4. Biomet's Motion to Exclude Portions of Ms. Truman's Testimony [Doc. 111]

Ms. Truman is a biomedical engineer with expertise in the fields of biomechanics and orthopedics. Ms. Truman sought to "determine if Biomet products implanted in Lynwood Hardison were unreasonably dangerous and defective and in a manner that caused premature failure." [Doc. 108-18, p. 4]. In her report, she concluded that the M2a Magnum was unreasonably dangerous and defective in design, thereby causing Plaintiff's injury. [*Id.,* pp. 105—111]. Ms. Truman generally opined that the metal-on-metal articulation in the M2a Magnum generates huge numbers of wear debris due to various design defects, including poor lubrication and the large femoral head having

higher frictional torques.[12] [Doc. 108-18., pp. 4—5, 105—06 (providing a general overview of alleged design defects)].

Additionally, Ms. Truman opined that "M2a Magnum Hip System had several warning defects" including failure to provide warnings "in formats normally reviewed by surgeons such as surgical techniques, surgeon-to-surgeon training talks or brochures." [Doc. 138-4, p. 109].

Biomet seeks to exclude Ms. Truman's medical causation opinions and opinions related to the device's corrosion and design tolerance. [Doc. 111-1, p. 2].

a. Medical Causation Opinions

First, Biomet correctly contends Ms. Truman is not qualified to make medical causation opinions. [*Id.*, pp. 7—10]; [Doc. 111-4, Truman Depo., p. 72:8—17 (Ms. Truman stated she only intends to offer "biomedical engineering-related opinions")]. Ms. Truman does not have the requisite medical background, and the Court excludes all of her medical causation opinions on that basis. *See In re Biomet M2a Magnum Hip Implant Products Liability Litigation*, No. 3:12-MD-2391, 2017 WL 10845178, at *15 (N.D. Ind. 2017).

Accordingly, Ms. Truman cannot provide medical causation opinions, including that the design defect contributed to Mr. Hardison's death, injuries, and need for

[12] Further, Ms. Truman provided rationales for ruling out patient factors, like obesity, falls, and lumbar issues, as sole causes of device failure. [Doc. 138-13, pp. 6—8].

revision surgery. To the extent Ms. Truman reiterates medical professionals' opinions in her report, medical experts would more appropriately establish those opinions. Once those medical professionals have established that opinion, Ms. Truman is entitled to rely on those opinions for her analysis.

b. Biomechanical Opinions

Next, Biomet seeks to exclude Ms. Truman's opinion "that there was corrosion in Mr. Hardison's device" and opinions "as to taper mismatch in this case." [Doc. 111-1, pp. 13, 15].

i. Corrosion Opinion

As to the corrosion in the device, Biomet argues that Ms. Truman's failure to test—when Ms. Truman had the opportunity to do so—Mr. Hardison's device for corrosion renders her corrosion opinions inadmissible speculation. [Doc. 164, p. 7]. Plaintiff argues that, despite not testing Mr. Hardison's device, Ms. Truman sufficiently based her opinion on data, her professional experience, and her visual inspection of the device. [Doc. 132, pp. 16—17].[13] Ms. Truman's rationale for not testing for corrosion was that she already "kn[e]w there was significant corrosion. So I didn't feel it was needed." [Doc. 111-4, Truman Depo., p. 229:23—24]. Ms. Truman additionally stated there is evidence of clinically significant taper corrosion "because of the [observed] cold-

[13] Ms. Truman's visual inspection alone would be insufficient. [Doc. 111-4, Truman Depo., p. 230:10—17 (Ms. Truman stated that she can't rule out the "visible corrosion" being "biological deposits . . . without doing the analysis")].

welding." [*Id.*, p. 158:4—15]. Here, Ms. Truman's opinion is based on more than mere speculation after visually inspecting the device, and she cites to scientific literature to support her conclusion. [*Id.*, p. 60:18—19 (Ms. Truman stated she relied on what she examined being consistent with the scientific literature.)]. Thus, the Court will not exclude Ms. Truman's corrosion opinion. The Court remains confident that a thorough and sifting cross examination will sufficiently allow Biomet to point out any criticism it may have regarding her lack of testing.

ii. Taper Mismatch Opinion

As to the taper mismatch opinion, Ms. Truman opined that "both modular taper interfaces in the M2a Magnum femoral head are because the production prints *allowed* a taper mismatch > 4'30"." [Doc. 111-2, p. 9 (emphasis added)]. Biomet seeks to exclude this opinion because Ms. Truman only testifies the device's production prints allowed for a mismatch and has no basis for determining that Mr. Hardison's device had a mismatch. [Doc. 164, pp. 8—9].

In her deposition, Ms. Truman explained that her taper mismatch opinion is relevant because "Mr. Hardison's head would not come off" and his clinical cold welding was because of the "taper design and misfit". [Doc. 138-5, Truman Depo., p. 157:12—19]. Further, Ms. Truman stated, regarding optimization of tapers, "there was not an effort [by Biomet] to do any testing or optimization to minimize the risk for this cold-welding, which is a corrosion at the interface." [*Id.*, p. 157:22—25]. She also stated

that this mismatch would be significant because "you get more mechanically assisted crevice corrosion when there is a larger taper mismatch" and "more fretting and more motion at those interfaces, and there are higher stresses imparted." [*Id.*, p. 164:5—16].

When asked if she knew that there was a taper mismatch in Mr. Hardison's device, Ms. Truman responded, "[f]irst, there is always going to be a taper mismatch. There is never anything perfect. There is no perfect. But I don't know that there was a greater than 4 degrees, 30 minutes. I am saying that's a design defect, but I don't know specifically what his was." [*Id.*, pp. 164:18—165:2]. Further, Ms. Truman admitted to not doing "destructive testing" because "when you have that level of corrosion, that you have a clinical cold-weld, you cannot find that on damaged surface, but I can't tell you what we would find without doing the destructive analysis." [*Id.*, pp. 164:18—165:2].

Biomet argues that "without knowing whether Mr. Hardison's M2a Magnum device actually had a clinically significant taper mismatch, there is no basis to establish the relevance of Ms. Truman's taper mismatch opinions."[14] [Doc. 164, pp. 8—9]. Plaintiff asserts that Ms. Truman can show a large taper misfit because of the "finding of [clinical cold welding], her visual inspection of the device components and her review of" the scientific and medical literature. [Doc. 132, p. 17]; *see also* [Doc. 111-4, Truman Depo., p.

[14] Further, Dr. Kurtz, in his expert report, considers Ms. Truman's opinion "highly speculative" and argues that Ms. Truman's "performed no testing or analysis to demonstrate that tolerances . . . are causally related to material loss and corrosion during clinical use. Furthermore, she has no data, one way or another, related to where within the tolerance range the components are manufactured." [Doc. 109-7, p. 56].

163:17—19 (Ms. Truman stated that "[b]ased on my training, background, experience, and working on devices, it is highly likely there was a mismatch")]. The Court finds this basis overly speculative and insufficient to conclude there was a taper mismatch greater than 4 minutes and 30 seconds in Mr. Hardison's device. Accordingly, the Court excludes Ms. Truman's taper mismatch opinion.

5. Plaintiff's Motion to Exclude Portions of Dr. Kurtz's Testimony [Doc. 118]

Plaintiff seeks to exclude Dr. Kurtz's, a biomedical engineer, opinion that (1) "Mr. Hardison's revision surgery was due to the [M2a Magnum] experiencing higher than expected wear, as a result of the combination of certain patient and clinical factors" and (2) "the use of an alternative hip implant would not have averted Mr. Hardison's need for revision surgery due to his clinical, patient, and implant factors." [Doc. 118-1, p. 3].[15] Plaintiff's arguments for exclusion are essentially that Dr. Kurtz cannot quantify the extent the factors caused increased debris wear and failed to sufficiently consider relevant evidence in Mr. Hardison's medical record concerning the patient factors Dr. Kurtz opined played a role in the higher than expected metal wear: history of falling, high body mass, activity levels, and lumbar and sacral fusion. [*Id.*, pp. 3, 5].

[15] As Plaintiff failed to cite to any authority regarding her request to exclude Dr. Kurtz's alternative hip implant theory, the Court will assume that Plaintiff's arguments for excluding both opinions are the same.

As to the history of falls, Dr. Kurtz did not fully consider Mr. Hardison's early fall history being from seated positions. [*Id.*, pp. 6—7 (citing [Doc. 114-2, Kurtz Depo., pp. 121:19—122:2])]. Further, as to Mr. Hardison's body mass playing a role in metal wear, Dr. Kurtz could not reliably state how Mr. Hardison's use of an assistive walker or wheelchair would reduce his load and the wear on the device. [*Id.*, pp. 7—8 (citing [Doc. 114-2, Kurtz Depo., pp. 154:5—25, 169:17—25])]. Third, as to Mr. Hardison's activity levels, Dr. Kurtz could not quantify how active Mr. Hardison was leading up to the revision surgery. [*Id.*, pp. 8—9 (citing [Doc. 114-2, Kurtz Depo., pp. 130:18—131:8])]. Fourth, Dr. Kurtz asserted that abnormal hip biomechanics lead to "relatively minor contribution to his in vivo wear rate[,]" but admitted he cannot opine about the extent abnormal biomechanics would be able to reduce wear. [*Id.*, pp. 9—10 (citing [Doc. 108-7, p. 52] and [Doc. 114-2, Kurtz Depo., p. 130:3—17])]. Fifth, Dr. Kurtz stated that his 2007 and 2011 spine procedures could have been another source of cobalt and chromium debris but did not know whether those surgeries could have resulted in chromium or cobalt deposits. [*Id.*, pp. 11—12 (citing [Doc. 114-2, Kurtz Depo., pp. 133:11—134:9])].

These opinions and rebuttal arguments go to the weight, not the admissibility of the evidence. Dr. Kurtz sufficiently identified factors that could result in greater than normal wear and explained his rationale for why those factors could apply to Mr. Hardison. Accordingly, the Court will not exclude Dr. Kurtz's opinion as to these factors contributing to higher than normal wear. However, Dr. Kurtz's inability to

quantify the extent to which these factors caused metal debris renders his opinions too speculative as to whether these factors could be the sole cause of higher than expected wear. While Dr. Kurtz can opine that these factors can contribute to higher than normal wear, he cannot opine that these factors were the only cause of higher than normal metal debris. Likewise, the Court excludes Dr. Kurtz's opinion as to whether an alternative hip implant would have averted Mr. Hardison's need for revision surgery because he did not show patient factors caused the hip implant to fail.

6. Plaintiff's Motion to Exclude Portions of Dr. Bauer's Testimony [Doc. 119]

Plaintiff seeks to exclude Dr. Bauer's opinions (1) about the possibility of an infection before Mr. Hardison's revision surgery based on an August 2015 pathology report and two lab tests from September 2015 and (2) that Mr. Hardison's diabetes was poorly controlled based on laboratory tests. [Doc. 119-1, pp. 3, 10].

As to Dr. Bauer's infection opinion, Plaintiff argues that Dr. Bauer did not look at all of the pertinent medical records and, specifically, Dr. Raurk's treatment records, including his determination that there was no sign of infection on September 28, 2015. [*Id.*, pp. 3, 9]. But any unfamiliarity with the medical record goes to the credibility of the expert's resulting opinions, not the admissibility. If other evidence exists outside of what Dr. Bauer reviewed, Plaintiff may use this evidence on cross-examination to undermine Dr. Bauer's credibility. Thus, the Court concludes that—while Plaintiff may raise her concerns about Dr. Raurk's testimony at trial—Plaintiff failed to show Dr.

Raurk's infection opinion is not based on a reliable methodology; accordingly, the Court will not exclude his opinion. *See Daubert*, 509 U.S. at 595 (stating courts must focus "solely on the principles and methodology [of the experts], not on the conclusions that they generate").

As to Dr. Bauer's diabetes opinion, Plaintiff argues it is outside of Dr. Bauer's expertise. Specifically, Plaintiff seeks to exclude the following opinion:

> Mr. Hardison's elevated HbA1C (7.2) on September 17, 2015 reflected suboptimal control of his diabetes. Patients with poorly controlled diabetes are at increased risk for complication, including infection.

[Doc. 119-1, p. 10 (citing [Doc. 115-1, p. 25])]. Biomet concedes that "Dr. Bauer does not treat diabetic patients, does not prescribe diabetic medications, and does not hold himself out as an internal medicine specialist" but responds that Dr. Bauer's expertise in pathology with 35 years of experience qualify him to make basic inferences from reviewing Mr. Hardison's lab tests, including supervising the lab that performs diabetes tests. [Doc. 127, pp. 8—9]. The Court finds Dr. Bauer's experience qualifies him to render this diabetes opinion. *Frazier*, 387 F.3d at 1260 (stating experts "may be qualified in various ways" including experience). Accordingly, the Court will not exclude this opinion.

B. Mr. Hardison's Treating Physicians Can Opine About Diagnosis and Treatment

Before discussing the viability of Plaintiff's claims, the Court examines whether Plaintiff's treating physicians can provide any causation opinions. Biomet contends that

"Plaintiff did not timely or properly disclose Mr. Hardison's treating physicians as experts and their testimony should be limited to the facts of the case." [Doc. 160, p. 2]. In a hearing on the matter, Plaintiff argues that she has complied with the disclosure requirements because Biomet deposed the treating physicians and, thus, they were identified by deposition and should be permitted to testify. *Video Conference Motions Hearing before the Honorable Tilman E. Self, III*, (M.D. Ga. May 20, 2020) (audio recording on file with clerk); [Doc. 168, p. 2]. Biomet does not contest that Plaintiff's treating physicians can testify and only contends that they cannot opine about causation or provide expert testimony. [Doc. 160, p. 2].

The Court finds Plaintiff did not disclose Mr. Hardison's treating physicians as experts. *See generally* [Doc. 108-13]. "A party must disclose to other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705." Fed. R. Civ. P. 26(a)(A). "Treating physicians not disclosed as experts are limited to testimony based on personal knowledge and may not testify beyond their treatment of a patient." *Rangel v. Anderson,* 202 F.Supp.3d 1361, 1364 (S.D. Ga. 2016) (citing *Kondragunta v. Ace Doran Hauling & Rigging Co*., No. 1:11–cv–01094, 2013 WL 1189493, at *3 (N.D. Ga. Mar. 21, 2013)); *Guevara v. NCL (Bahamas) Ltd*., 920 F.3d 710, 718 (11th Cir. 2019) ("Courts have broad discretion to exclude untimely expert testimony"). Accordingly, Plaintiff's treating physician testimony will be limited to their personal knowledge.

As the Eleventh Circuit noted in *Wilson*:

> A treating physician may testify as a lay witness regarding his observations and decisions during treatment of a patient, once the treating physician expresses an opinion unrelated to treatment which is "based on scientific, technical, or other specialized knowledge," that witness is offering expert testimony for which the court must perform its essential gatekeeping function as required by *Daubert*

Wilson v. Taser Int'l, Inc., 303 F.App'x 708, 712 (11th Cir. 2008) (citing *United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005)). Accordingly, the Court in *Wilson* found "[t]estimony regarding [the treating physician's] diagnosis of the injury itself—that Wilson's spine was fractured—would be permissible as lay testimony without the *Daubert* analysis, but his statement about the cause of the injury was an hypothesis." *Wilson*, 303 F.App'x at 712—13.

Plaintiff argues that Mr. Hardison's treating physicians still ought to be able to give causation opinions because their testimony "as to causation is well within Mr. Hardison's diagnosis, prognosis, and treatment." *See* [Doc. 135-1, pp. 16—19]. Plaintiff points to several of the treating physicians' causation-related statements that the Court discusses below.

First, when Dr. Raurk was asked why he recommended revision surgery for Mr. Hardison's hip implant, he stated, "[b]ecause I felt that that was likely to have caused his soft tissue damage, and I'm pretty aggressive with metal-on-metal problems." [Doc. 139-14, Raurk Depo., p. 46:5—14]. The Court permits Dr. Raurk to discuss his observations; however, Dr. Raurk's attempt to identify the cause of the soft tissue

damage was clearly a hypothesis that ought to have been disclosed to Biomet. Accordingly, the Court will not allow Dr. Raurk to provide this causation opinion.

Second, Dr. Flandry stated (1) he observed signs of metallosis, (2) he thought Mr. Hardison was early into a metal disease, and (3) he planned to "refer him to one of my partners, who specialized in revising metal-on-metal problem hips." [Doc. 139-13, Flandry Depo., p. 26:3—14]; *see also* [*Id*., p. 24:8—12 (stating he presumed the metallosis came from the hip implant)]. Again, the Court permits Dr. Flandry to discuss what he observed, but he may not testify as to what caused the metal debris.

Dr. Warnock—Mr. Hardison's primary care physician at the nursing home where he resided when he died—stated that it was "difficult to characterize" Mr. Hardison's hip problems and he "just needed to know what happened, and, if possible, why, and then what it meant so far as his current functioning level was concerned." [Doc. 139-15, Warnock Depo., pp. 26:15—27:7]; *see also* [*Id*., p. 44:6—10 (opining the hip surgery, hip abductor damage, and post revision infection affected his stability)]; *see also* [*Id*., p. 70:7—25 (opining "you could say" his hip injuries "played a role" in his ultimate death)]; [Doc. 134, p. 13 (explaining Dr. Warnock's role in Mr. Hardison's treatment)]. These causation opinions are inadmissible since the hypotheses for Mr. Hardison's injuries and death were not needed to diagnose and treat his injuries.

Having ruled on the parties' *Daubert* motions and discussed Plaintiff's treating physician testimony, the Court turns to Biomet's Motion for Summary Judgment.

C. Biomet's Motion for Summary Judgment [Doc. 108]

1. Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is genuine if the evidence would allow a reasonable jury to return a verdict for the nonmovant and a fact is material if it "might affect the outcome of the suit." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In considering this motion, "the evidence of the [nonmovant] is to be believed, and all justifiable inferences are to be drawn in [the nonmovant's] favor." *Id.* at 255. However, the Court need not draw "all possible inferences" in favor of the nonmovant. *Horn v. United Parcel Servs., Inc.*, 433 F. App'x 788, 796 (11th Cir. 2011).

The movant "bears the initial burden of informing the district court of the basis for its motion[] and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Jones v. UPS Ground Freight*, 683 F.3d 1283, 1292 (11th Cir. 2012) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmovant "to rebut that showing by producing affidavits or other relevant and admissible evidence beyond the pleadings." *Jones*, 683 F.3d at 1292 (quoting *Josendis v. Wall to Wall Residence Repairs, Inc.*, 662 F.3d 1292, 1315 (11th Cir. 2012)).

2. Analysis

Plaintiff concedes to the dismissal of Counts 3, 7, and 8 concerning Plaintiff's claims for breach of express and implied warranties. Plaintiff also concedes to the dismissal of part of Count 5, her claim for manufacturing negligence. Plaintiff's remaining claims are for design defect, failure to warn, violation of GFBPA, negligence in design and warning, loss of consortium, and wrongful death. Biomet moves for the Court to dismiss these claims and Plaintiff's request for punitive damages and attorneys' fees.

a. Design Defect Claims

Biomet argues it is entitled to summary judgment on Plaintiff's design defect claims because she cannot prove medical causation. "In cases where a jury is asked to assess complex medical or scientific issues outside the scope of a layperson's knowledge, an expert's testimony is required." *McCasland v. Pro Guard Coatings, Inc*., 799 F.App'x 731, 733 (11th Cir. Jan. 23, 2020) (collecting cases finding medical experts were needed to establish a causal link between an injury and the medical device). "Specific causation refers to the issue of whether the plaintiff has demonstrated that the substance [or device] actually caused injury in her particular case." *Guinn*, 602 F.3d at 1248 n. 1. Plaintiff submitted three experts to testify regarding specific causation: Dr. Shapiro, Ms. Truman, and Dr. Gannon. "[C]ausation may be established by linking the testimony of several different experts" and "must be determined in light of the

evidentiary record as a whole." *Central Ga. Women's Health Center v. Dean*, 800 S.E.2d 594 (Ga. Ct. App. 2017) (quoting *Walker v. Giles*, 624 S.E.2d 191, 199 (Ga. Ct. App. 2005).

When viewing all reasonable inferences in Plaintiff's favor, she has sufficiently provided causation testimony that links a defect in the device to some of Mr. Hardison's injuries. First, Ms. Truman opined that a device defect caused the device to fail. Second, Plaintiff's medical experts sufficiently opined that the metal debris led to necrosis, tissue damage, need for revision surgery, and post-revision surgery medical issues.

Accordingly, the Court **DENIES** Biomet's motion for summary judgment as to Plaintiff's claims for design defect based on negligence and strict liability.

b. Failure-to-Warn Claims

Biomet also argues Plaintiff's failure-to-warn claims are due to be dismissed. As previously discussed, Plaintiff's only viable failure-to-warn claims are in the form of a failure to communicate a warning because Dr. Pope testified he did not read the warning. *Brown*, 2017 WL 4082690, at *5; *Bryant*, 9 F. Supp. 3d. at 1395 (quoting *Turner*, 460 S.E.2d at 534) ("[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk[.]"). This District has considered failure-to-communicate claims—where a doctor did not read a warning inside the packaging—and permitted the claim to proceed. *In re Mentor Corp. Obtape Transobturator Sling Prod. Liab. Litig.*, No. 4:08-MD-2004 (CDL), 2015 WL 5139616, at *3 (M.D. Ga. Sept. 1, 2015).

"In standard products liability cases premised on a failure to warn, Georgia law insists that a plaintiff show that the defendant had a duty to warn, that the defendant breached that duty, and that the breach proximately caused the plaintiff's injury." *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (citing *Wheat v. Sofamor,* S.N.C., 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999)); *Cisson v. C.R. Bard, Inc.*, No. 2:11–cv–00195, 2013 WL 5700513, at *8 (S.D.W. Va. Oct. 18, 2013) ("Proving causation [under Georgia law] consists of . . . the plaintiffs [showing] that Dr. Raybon would not have implanted the Avaulta Plus if Bard had provided the warnings the plaintiffs allege should have been provided.").

Under Georgia's learned-intermediary doctrine, a medical device manufacturer "does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 711 F.Supp.2d 1348, 1365—66 (M.D. Ga. 2010) (quoting *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003)). "The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ [a medical device] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities." *Id*. at 1366 (quoting *McCombs*, 587 S.E.2d at 595). The warnings to the doctor "must be adequate or reasonable under the circumstances of

the case." *Id*. (quoting *McCombs*, 587 S.E.2d at 595). The first step is to determine whether the manufacturer provided the learned intermediary an adequate warning. *Id.* at 1366. "If the warning was inadequate, the plaintiff must show that the deficient warning proximately caused the alleged injury to prevail." *Id.*

Plaintiff has presented admissible expert testimony, including (1) Ms. Truman's opinion that Biomet did not properly communicate the device warnings, (2) Dr. Shapiro's testimony that a surgeon would not have used the M2a Magnum if given a proper warning, (3) Dr. Gannon and Dr. Shapiro's testimony regarding medical causation. Thus, Plaintiff has sufficiently provided medical causation evidence as to whether the device generated metal debris and resulted in injury.

Thus, Plaintiff has sufficiently provided evidence and expert testimony regarding how Biomet should have communicated the warnings. Accordingly, the Court **DENIES** Biomet's motion for summary judgment as to Plaintiff's failure-to-warn claims based on negligence and strict liability.

c. Negligent Misrepresentation Claim

For Plaintiff's negligent misrepresentation claim, she asserts that "Defendants supplied false information to the Plaintiff and his implanting physician, Dr. Pope, about the high quality, safety and effectiveness of the Magnum M2a device even though they knew this was not the truth." [Doc. 135-1, p. 35].

Under Georgia law, the elements for negligent misrepresentation are "(1) the defendant's negligent supply of false information to foreseeable persons, known or unknown; (2) such persons' reasonable reliance upon that false information; and (3) economic injury proximately resulting from such reliance." *Next Century Commc'ns Corp. v. Ellis,* 318 F.3d 1023, 1030 (11th Cir. 2003) (applying Georgia law); *see also Lafontaine v. Alexander*, 808 S.E.2d 50, 55 (Ga. Ct. App. 2017) ("The elements of a negligent misrepresentation claim are (1) a false representation o[r] omission of a material fact; (2) scienter; (3) intention to induce the party claiming fraud to act or refrain from acting; (4) justifiable reliance; and (5) damages."); *see also Anderson v. Atlanta Comm. for Olympic Games, Inc*., 584 S.E.2d 16, 21 (Ga. Ct. App. 2003) (stating that "justifiable reliance is an essential element of a claim asserting negligent misrepresentation"). Federal courts in Georgia have found negligent misrepresentation claims are not distinct from failure-to-warn claims unless Plaintiff explains otherwise.[16] *See Brazil v. Janssen Research & Development, LLC,* No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *1 (N.D. Ga. 2016) (finding—in the absence of clear precedent—that misrepresentation claims are not distinct from failure-to-warn claims unless explained otherwise); *Swicegood v. Pliva, Inc*., 543 F.Supp.2d 1351, 1357 (N.D. Ga. 2008) (same); G*addy v. Terex Corp*., 1:14-cv-1928-WSD, 2017 WL 3476318, at *5 (N.D. Ga. 2017) (same).

[16] Biomet argues this claim is duplicative of Plaintiff's failure-to-warn claim and, accordingly, is due to be dismissed. [Doc. 160, p. 9]. But, as noted above, Plaintiff has presented sufficient evidence to survive summary judgment on her failure-to-warn claim.

The Court agrees that Biomet omitting any warning would also be encompassed in a failure-to-warn claim.

But Plaintiff also points to statements made by a Biomet sales representative that she alleges were false. Dr. Pope stated that the "concern at the time was wear debris, the metal ions and wear debris, and what does that effect have on the body . . . But the assurance [provided by Biomet's representatives] was that . . . the wear debris of this particular implant was – was far less and [Biomet wasn't] seeing problems with it." [Doc. 137-5, Pope Depo., pp. 24:19-27:9]. This assurance could present a distinct claim from Plaintiff's claims for failure to communicate a warning because regardless of how Biomet should have communicated the warning, a defendant still cannot make false statements to induce a sale. Further, Plaintiff has presented some evidence that Biomet's representatives should have known its claim that the hip implant wasn't having issues was false. [Doc. 135-1, pp. 24—28]; *see* [Doc. 152]. Only a jury can resolve this issue.

Accordingly, the Court **DENIES** Biomet's motion for summary judgment as to Plaintiff's claim for negligent misrepresentation.

d. Georgia Fair Business Practices Act Claim

Biomet argues that Plaintiff's GFPBA claim is due to be dismissed because Plaintiff failed to provide notice. [Doc. 160, p. 8]. The elements of a GFBPA claim are: (1) a violation of the GFBPA; (2) causation; and (3) injury. *Tiismann v. Linda Martin Homes Corp.*, 637 S.E.2d 14, 17 (Ga. 2006). If a claimant alleges that a defendant violated the

GFBPA as a result of a misrepresentation, the claimant must demonstrate that he was injured as the result of his intermediary's reliance upon the alleged misrepresentation. *Id.* at 16; *Zeeman v. Black*, 273 S.E.2d 910, 916 (Ga. Ct. App. 1980) (providing that when the alleged violation of the GFBPA is a misrepresentation, the Act "incorporat[es] the 'reliance' element of the common law tort of misrepresentation into the causation element of an individual claim").

Further, the GFBPA requires a plaintiff to provide a written demand for relief at least 30 days before filing suit to be entitled to an award of damages unless the "prospective respondent does not maintain a place of business or does not keep assets within the state." O.C.G.A. § 10-1-399(b). Plaintiff does not argue that Biomet maintains no assets in Georgia and did not provide notice before filing suit in the MDL because Plaintiff argues filing into the MDL was Biomet's notice. *See* [Doc. 135-1, p. 31]. But the filing of a suit—into the MDL or otherwise—still requires notice, and Plaintiff has cited to no legal authority to support her claim that she properly gave notice. Thus, Plaintiff's GFBPA claim is due to be dismissed for her failure to give notice. Likewise, Plaintiff's request for attorneys' fees under the GFBPA also fails.

Accordingly, the Court **GRANTS** Biomet's motion for summary judgment as to Plaintiff's GFBPA claim.

e. Loss of Consortium Claim

Biomet moves to dismiss Plaintiff's loss of consortium claim because it is derivative of Plaintiff's other claims. [Doc. 112, pp. 9, 35]; *see Miller v. Crumbley*, 548 S.E.2d 657 (Ga. Ct. App. 2001) (Under Georgia law, "a loss of consortium claim is derivative of the spouse's personal injury action."). The Court has determined that Plaintiff has presented sufficient evidence for several claims so that her individual loss of consortium also survives.

Accordingly, the Court **DENIES** Biomet's motion for summary judgment as to Plaintiff's claim for loss of consortium.

f. Punitive Damages

Biomet argues that Plaintiff provided insufficient conclusory evidence for punitive damages. [Doc. 112, p. 36]. Specifically, Biomet asserts that Plaintiff fails to provide sufficient evidence that Biomet committed misconduct willfully or with conscious indifference. [*Id*., pp. 36—37].

In Georgia, there may be an award for punitive damages in a tort action only if "it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A. § 51–12–5.1(b). A plaintiff must show more than gross negligence to receive punitive damages because punitive damages are designed to punish wrongdoing by the

defendant, not compensate the plaintiff for his injuries. *Mastec N. Amer., Inc. v. Wilson,* 755 S.E.2d 257, 259—260 (Ga. Ct. App. 2014); O.C.G.A. § 51–12–5.1(c).

Generally, punitive damages are not appropriate in cases where a manufacturer complies with regulatory standards. *Welch v. Gen. Motors Corp*., 949 F.Supp. 843, 845—46 (N.D. Ga. 1996) (citing *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993)). However, that rule is not hard and fast, particularly where the manufacturer's conduct shows some wanton or otherwise culpable behavior. Here, there is a genuine issue of material fact that Biomet was aware of and ignored the issues with the M2a Magnum. [Doc. 135-1, pp. 24—28]; *see* [Doc. 149]; [Doc. 150]; [Doc. 151]; [[Doc. 152]; [Doc. 153]; [Doc. 154]; [Doc. 155]; [Doc. 156]. In short, Plaintiff has pointed to evidence that Biomet knew of issues with the M2a Magnum but decided against disclosing that information. Accordingly, the Court **DENIES** Biomet's motion for summary judgment as to punitive damages at this time**.**

g. Wrongful Death Claim

Plaintiff's wrongful death claim fails because there is no admissible evidence of medical causation to show that the implant caused Mr. Hardison's death. The Court excluded portions of Dr. Shapiro and Dr. Gannon's testimony that attempted to link Mr. Hardison's hip implant injuries with his death. Further, Mr. Hardison's treating physicians may not testify as to whether the issues with the M2a Magnum caused his

death. Accordingly, the Court **GRANTS** Biomet's motion for summary judgment as to Plaintiff's wrongful death claim.

CONCLUSION

To the extent described in this Order, Biomet's motions to exclude testimony from Dr. Gannon [Doc. 109], Ms. Truman [Doc. 110], and Dr. Shapiro [Doc. 111] are **GRANTED in part and DENIED in part**, and the Court considered Plaintiff's expert witness testimony in ruling on Biomet's motion for summary judgment.

Further, the Court **GRANTS in part** and **DENIES in part** Plaintiff's motions to exclude portions of Dr. Kurtz's testimony [Doc. 118] and **DENIES** Plaintiff's motion to exclude portions of Dr. Bauer's testimony [Doc. 119] as outlined in this Order.

Finally, the Court **GRANTS in part** and **DENIES in part** Biomet's summary judgment motion [Doc. 108]. Plaintiff's claims for failure to warn, design defect, negligent design and warning, negligent misrepresentation, loss of consortium, and punitive damages shall proceed to trial. However, the Court dismisses Plaintiff's claims for manufacturing negligence, violation of GFBPA and related attorneys' fees, breach of express and implied warranties, and wrongful death.

SO ORDERED, this 27th day of July, 2020.

S/ Tilman E. Self, III
TILMAN E. SELF, III, JUDGE
UNITED STATES DISTRICT COURT